IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8420

Bartle, C.J. March 9, 2010

The Estate of Michelle T. Brown (the "Estate" or "representative claimant"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Joseph E. Brown, Michelle T. Brown's ("Ms. Brown" or "decedent") spouse, and MacKenzi C. Fischer and Bailey P. Brown, Ms. Brown's children, also have submitted derivative claims for benefits.

3. Matrix Benefits are paid according to two benefit matrices

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To seek Matrix Benefits, a representative claimant[4] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the deceased's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the attorney for the representative claimant must complete Part III if claimant is represented.

In July, 2001, Joseph Brown, Administrator of the Estate of Michelle Brown, submitted a completed Green Form to the Trust signed by the attesting physician, Joel K. Kahn, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated December 23,

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3. (...continued)
(Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § 11.B.

1997, Dr. Kahn attested in Part II of the Green Form that Ms. Brown suffered from mild mitral regurgitation and endocardial fibrosis.[5] Based on such findings, the Estate would be entitled to Matrix A-1,[6] Level V benefits in the amount of $1,351,132.[7]

In the report of Ms. Brown's echocardiogram, Richard A. Fell, M.D., the reviewing cardiologist, observed that Ms. Brown had "[b]orderline concentric hypertrophy of the left ventricle with a dilated left ventricle and moderate left ventricular dysfunction secondary to hypokinesis of the interventricular

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5. In addition, Dr. Kahn attested that Ms. Brown suffered from an abnormal left ventricular end-systolic dimension, a reduced ejection fraction of less than 30%, and New York Heart Association Functional Class III symptoms. These conditions, however, are not at issue in this claim.

6. Dr. Kahn also attested that Ms. Brown suffered from mitral valve prolapse, which, under the Settlement Agreement, requires the payment of reduced Matrix Benefits for mitral valve claims. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b). The auditing cardiologist, however, found that there was no reasonable medical basis for Dr. Kahn's representation. Although the Trust stated in its final post-audit determination that the claim would be payable, if at all, on Matrix B, the Trust's Statement of the Case references payment only on Matrix A.

7. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered endocardial fibrosis diagnosed by: (1) an endomyocardial biopsy that demonstrates fibrosis and cardiac catheterization that demonstrates restrictive cardiomyopathy; or (2) an autopsy that demonstrates endocardial fibrosis. See Settlement Agreement § IV.B.2.c.(5)(a). In addition, a claimant or representative claimant must show that other causes, including dilated cardiomyopathy, myocardial infarction, amyloid, Loeffler's endocarditis, endomyocardial fibrosis as defined in Braunwald, focal fibrosis secondary to valvular regurgitation, focal fibrosis secondary to catheter instrumentation, and hypertrophic cardiomyopathy with septal fibrosis, have been excluded. See id.

septum." Dr. Fell also stated that his findings "suggest the presence of significant ischemic heart disease."[8] In the Case Summary on the Death of Michelle Brown attached to the Report of Autopsy, Diane Scala-Barnett, M.D., the examining deputy coroner, concluded that Ms. Brown's cause of death was dilated cardiomyopathy.

In May, 2004, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists.[9] In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Kahn's finding that dilated cardiomyopathy could be excluded as the cause of the decedent's endocardial fibrosis.[10] Dr. Churchwell stated that

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8. In the report of Ms. Brown's February 4, 1998 cardiac catheterization, Dr. Fell also noted that Ms. Brown suffered from "[d]iffuse hypokinesis of a dilated left ventricle with a visually estimated ejection fraction of 25-30%, compatible with dilated cardiomyopathy." Dr. Fell further observed, in the report of a December 18, 1998 echocardiogram, that Ms. Brown had "[d]ilated cardiomyopathy with global hypokinesis of the left ventricle with an estimated left ventricular ejection fraction of 25-30%."

9. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP") for Matrix claims asserting high-level medical conditions. As Wyeth did not agree that the Estate had a Matrix A-1, Level V claim, pursuant to the PPP, the Trust audited the Estate's claim.

10. Although Dr. Churchwell originally checked the box labeled "Yes" on the Attestation of the Auditing Cardiologist for whether there was a reasonable medical basis for Dr. Kahn's representation that Ms. Brown had endocardial fibrosis with the necessary causes excluded, his comments supported the conclusion that he did not find a reasonable medical basis for Dr. Kahn's representation. Additionally, Dr. Churchwell explained in a

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"THE is seen at the time of the autopsy. A small particle of fibrosis behind the posterior leaflet on the muscle. There is no evidence of restrictive cardiomyopothy by the study. She was [diagnosed] as having a dilated cardiomyopothy."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.[11] In contest, the Estate argues that the location of the fibrosis makes it "more likely than not" that the fibrosis is a result of Ms. Brown's ingestion of Diet Drugs and "eliminates and excludes dilated cardiomyopathy as a cause." In support, the Estate submitted a verified statement by Dr. Kahn, who notes, in pertinent part, that:

> The fibrosis was in association with a valvular structure, not randomly located within the endocardium distant from the muscle. It is more likely than not, in my expert opinion, that this position is related to the Redux and not just chance placement within the endocardium.

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10. (...continued)
supplemental declaration that he should have responded "No" to indicate that he did not find a reasonable medical basis for Dr. Kahn's finding.

11. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

The Estate also noted that, contrary to the auditing cardiologist's characterization, the Report of Autopsy does not describe the endocardial fibrosis seen behind the posterior leaflet as a "small particle."

The Trust then issued a final post-audit determination, again denying the Estate's claim. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5246 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on November 17, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[12] to review claims

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and representative claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Brown was diagnosed by autopsy as having endocardial fibrosis with dilated cardiomyopathy having been excluded as a cause. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate repeats the arguments it made in contest. Specifically, it argues that there is a reasonable medical basis for Dr. Kahn's representation that Ms. Brown had endocardial fibrosis, which was not caused by dilated cardiomyopathy, because Dr. Kahn opined that the location of the endocardial fibrosis behind the posterior leaflet

"excludes the alternate cause of dilated cardiomyopathy." In addition, the Estate suggests that the issue is not whether the autopsy includes a diagnosis of dilated cardiomyopathy but, rather, whether a reasonable medical basis exists to exclude dilated cardiomyopathy as a cause of Ms. Brown's endocardial fibrosis.

In response, the Trust argues that the Estate has not met its burden because, based on the information contained in Ms. Brown's death certificate and the Case Summary on the Death of Michelle Brown, dilated cardiomyopathy cannot be excluded as a cause of the decedent's endocardial fibrosis. The Trust also argues that Dr. Kahn did not "explicitly eliminate or exclude dilated cardiomyopathy" as a cause of the decedent's endocardial fibrosis.

The Technical Advisor, Dr. Abramson, reviewed the Show Cause Record and concluded that there was no reasonable medical basis for the attesting physician's representation that Ms. Brown suffered from endocardial fibrosis and that such condition was not caused by dilated cardiomyopathy. Dr. Abramson explained:

> I reviewed the transthoracic echocardiogram dated 12/23/97 which reveals a markedly dilated left ventricle with severely decreased systolic function consistent with a dilated cardiomyopathy. There is no evidence of a restrictive cardiomyopathy on the echo. This would appear as a normal-sized left ventricle with normal or mildly decreased systolic function usually associated with at least moderate valvular regurgitation.
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> The presence of endocardial fibrosis on the autopsy is a very non-specific finding found

> in any heart that has sustained damage. Thus, a patient with a dilated cardiomyopathy will have fibrosis seen on autopsy.
>
> In conclusion, Michelle T. Brown had a dilated cardiomyopathy documented by echo, cardiac catheterization, and autopsy. There is no evidence of a restrictive cardiomyopathy on any of these studies. The non-specific finding of fibrosis on autopsy does not support any specific diagnosis. Thus, because a dilated cardiomyopathy is present, there is no reasonable medical basis for the Attesting Physician to answer 'yes' [sic] to Green Form Question L.6.

In response to the Technical Advisor Report, the Estate argues that Dr. Abramson incorrectly characterizes the finding in the Report of Autopsy as a "non-specific" finding of endocardial fibrosis. The Estate also suggests that a claimant could never exclude dilated cardiomyopathy as a cause of endocardial fibrosis if endocardial fibrosis is always seen in conjunction with a damaged heart. In addition, the Estate contends that Dr. Abramson does not address its contention that the location of Ms. Brown's endocardial fibrosis supports the conclusion that her ingestion of Diet Drugs, not dilated cardiomyopathy, was most likely the cause of her endocardial fibrosis.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As an initial matter, we reject its argument that Dr. Kahn's equivocal conclusion satisfies the criteria for Level V Matrix Benefits. Specifically, Dr. Kahn opined that "[t]he fibrosis was in association with a valvular structure, not randomly located within the endocardium distant from the muscle. It is more

likely than not, in my expert opinion, that this position is related to the Redux and not just chance placement within the endocardium." Notably, Dr. Kahn does not explain how or why the location of Ms. Brown's endocardial fibrosis excludes her undisputed dilated cardiomyopathy as a cause of the endocardial fibrosis. The Estate essentially requests that we write into the Settlement Agreement its understanding of the criteria for Level V Matrix Benefits. There is no basis for such a revision.

The Settlement Agreement specifically provides that a claimant will receive Level V Matrix Benefits if he or she suffers from endocardial fibrosis diagnosed by autopsy, when other causes, including dilated cardiomyopathy, have been excluded. Under this definition, Dr. Kahn's conclusion that Ms. Brown's ingestion of Diet Drugs, not dilated cardiomyopathy, was "most likely" the cause of her endocardial fibrosis is insufficient to qualify representative claimant for Level V Matrix Benefits.

We also disagree with the Estate's interpretation that Dr. Abramson's opinion states that "endocardial fibrosis is always seen in conjunction with a damaged heart" making it impossible for a claimant to exclude the "other causes" listed in the Settlement Agreement. As Dr. Abramson explained, "[t]he presence of endocardial fibrosis on the autopsy is a very non-specific finding found in any heart that has sustained damage. Thus, a patient with a dilated cardiomyopathy will have fibrosis seen on autopsy." Dr. Abramson does not state, contrary to

representative claimant's suggestion, that endocardial fibrosis is always seen in conjunction with the "other causes" required by the Settlement Agreement to be excluded. Rather, Dr. Abramson merely states that a patient who suffers from dilated cardiomyopathy will also have indications of fibrosis. The converse - that a patient who suffers from endocardial fibrosis necessarily will have dilated cardiomyopathy, or the other common causes of endocardial fibrosis - cannot fairly be gleaned from Dr. Abramson's opinion.

Finally, we reject the Estate's argument that Dr. Abramson did not address Dr. Kahn's opinion that the location of Ms. Brown's endocardial fibrosis excludes dilated cardiomyopathy as its cause. Indeed, Dr. Abramson specifically concludes that because dilated cardiomyopathy is present, there is no reasonable medical basis for the attesting physician's representation that dilated cardiomyopathy was excluded as a cause of Ms. Brown's endocardial fibrosis.

For the foregoing reasons, we conclude that the Estate has not met its burden in proving that there is a reasonable medical basis for its claim. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claims submitted by Ms. Brown's spouse and children.